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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,872	03/21/2006	Per Broberg	100924-1P US	3651
44992 7590 03/22/2010 ASTRAZENECA R&D BOSTON 35 GATEHOUSE DRIVE WALTHAM, MA 02451-1215				
EXAMINER				
KOSSON, ROSANNE				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
03/22/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,872

Applicant(s)

BROBERG ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The amendment filed on February 16, 2010, 2009 has been received and entered.

Claims 1 and 3-6 have been amended. No claims have been canceled or added. Accordingly, claims 1 and 3-6 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicants' amendments to the claims, the rejection in the previous Office action is replaced with the following rejection, as a different rejection now applies.

Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because they are drawn to a set of purified peptides identified in Table 1 or Table 2. But, the peptides (peptide numbers) listed in these tables are not physical peptides. These tables do not represent a composition comprising these peptides, i.e., a composition comprising somewhere between 20 and all of these peptides. What is listed in Tables 1 and 2 are the molecular weights (masses) of a number of fragments, as measured by mass spectrometry, the results of mass spectrometry experiments. Applicants have not made compositions comprising the peptides of Table 1 or Table 2. Some of these molecular weights correspond to molecular ions, molecules that are the digestion products of human elastin digested with MMP12 (a.k.a., human neutrophil elastase, human macrophage elastase, matrix metalloproteinase 12). Other molecular weights correspond to molecules that are fragments of these digestion products, fragments produced by the ionization process in

mass spec. Applicants have not produced compositions comprising the ionized fragments of the digestion products, and these numbers in the tables are data, not physical peptides or purified peptides. Further, it cannot be determined which peptides (as peptide numbers) correspond to the molecular ions and which correspond to their fragments. Clarification and appropriate are required.

Claim Rejections - 35 USC § 101

In view of Applicants' amendments to the claims, this rejection is withdrawn.

Claim Rejections - 35 USC § 102

In view of Applicants' amendments to the claims, the following rejection now applies.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kucich et al. (WO 91/18290 A1), as evidenced by Taddese et al. ("Mapping of macrophage elastase cleavage sites in insoluble human skin elastin," *Matrix Biology* 27:420-428, 2008).

As previously discussed, Kucich et al. disclose a composition derived from human urine comprising a set of purified naturally occurring fragments of elastin (see p. 4, first full paragraph, p. 7, first full paragraph, and p. 9, first full paragraph). Kucich et al. disclose that these elastin fragments are those that are detected by antibodies that were made against elastin fragments produced by digesting human elastin with human macrophage/neutrophil elastase (MMP12) (see p. 6, part II). Thus, the elastin fragments are those produced in vivo by digestion by MMP12. Kucich et al. do not disclose the number of elastin fragments that are produced, and the cleavage sites were not known at the time of Kucich et al. But, because elastin is digested by MMP12, inherently, all the naturally occurring fragments that correspond to all the molecular

ions listed in Applicants' Table 2 and identified by their molecular mass are produced and are present in the composition.

Taddesse et al. disclose that elastin has 36 cleavage sites and that, upon digestion with MMP12, more than 20 fragments (41 fragments) could be identified. More than 20 of these fragments have a molecular mass between roughly 750 and 3350 (see Abstract and p. 422, in particular Table 1), a range that is about the range shown in Table 2. Taddesse et al. used different mass spec techniques and instruments than Applicants, electrospray on an ion trap instrument and nanoESI on a qTOF mass spectrometer (see paragraph bridging pp. 421 and 422), while Applicants used a MALDI-TOF mass spectrometer (see p. 45 of the specification). Thus, the molecular masses measured are not identical. But, within a standard error of measurement, the molecular masses for the MMP12-digested elastin fragments of Taddesse et al. and Applicants appear to be the same.

In view of the foregoing, a holding of anticipation is required.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Tues., Wed., Fri., 8:30-6:00, Mon., 8:30-2:00, Thurs. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2010-03-02

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656